Complete Summary

GUIDELINE TITLE

Cost-benefit analysis of HPV vaccination. In: Canadian consensus guidelines on human papillomavirus.

BIBLIOGRAPHIC SOURCE(S)

Lalonde A. Cost-benefit analysis of HPV vaccination. In: Canadian consensus guidelines on human papillomavirus. J Obstet Gynaecol Can 2007 Aug;29(8 Suppl 3):S43-54. [29 references]

GUIDELINE STATUS

This is the current release of the guideline.

COMPLETE SUMMARY CONTENT

SCOPE

DISEASE/CONDITION(S)

Human papillomavirus infection

GUIDELINE CATEGORY

Management
Treatment

CLINICAL SPECIALTY

Family Practice
Infectious Diseases
Internal Medicine

Obstetrics and Gynecology
Pediatrics
Preventive Medicine

INTENDED USERS

Advanced Practice Nurses
Allied Health Personnel
Nurses
Physician Assistants
Physicians
Public Health Departments
Utilization Management

GUIDELINE OBJECTIVE(S)

To promote guidelines for health care providers on the key aspects of human papillomavirus (HPV) infection and the management of HPV-related disease in the new era of vaccine availability

TARGET POPULATION

Sexually active women and adolescent girls

INTERVENTIONS AND PRACTICES CONSIDERED

Human papillomavirus (HPV) vaccination of females aged 9 – 26 years against:

- High risk HPV types 16 and 18
- Low risk HPV types 6 and 11

MAJOR OUTCOMES CONSIDERED

- Clinical burden of human papillomavirus (HPV) infection
- Psychological burden of HPV-related disease
- Economic burden of HPV-related disease
- Cost-benefit analyses of HPV vaccination

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

Medline and Cochrane databases were searched for articles from January 1995 to March 2007 on subjects related to Human papillomavirus (HPV) infection, HPV vaccination, HPV-related disease, Pap testing, and specific consideration of management.

NUMBER OF SOURCE DOCUMENTS

Not stated

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Weighting According to a Rating Scheme (Scheme Given)

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Quality of Evidence Assessment*

I: Evidence obtained from at least one properly randomized controlled trial.

II-1: Evidence obtained from well-designed controlled trials without randomization.

II-2: Evidence obtained from well-designed cohort (prospective or retrospective) or case–control studies, preferably from more than one center or research group.

II-3: Evidence obtained from comparison between times or places with or without the intervention. Dramatic results in uncontrolled experiments (such as the results of treatment with penicillin in the 1940s) could also be regarded as this type of evidence.

III: Opinions of respected authorities, based on clinical experience, descriptive studies, or reports of expert committees.

* The quality of evidence reported in these guidelines has been adapted from The Evaluation of Evidence criteria described in the Canadian Task Force on Preventive Health Care.

METHODS USED TO ANALYZE THE EVIDENCE

Systematic Review

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

All study types were reviewed. Randomized controlled trial results were considered evidence of the highest quality, followed by results of cohort studies. Key individual studies on which the recommendations are based are referenced. Supporting data for each recommendation were summarized with evaluative comments and references.

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus

DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

Not stated

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Classification of Recommendations* †

A. There is good evidence to recommend the clinical preventive action

B. There is fair evidence to recommend the clinical preventive action

C. The existing evidence is conflicting and does not allow to make a recommendation for or against use of the clinical preventive action; however, other factors may influence decision-making

D. There is fair evidence to recommend against the clinical preventive action

E. There is good evidence to recommend against the clinical preventive action

I. There is insufficient evidence (in quantity or quality) to make a recommendation; however, other factors may influence decision-making

*Woolf SH, Battista RN, Angerson GM, Logan AG, Eel W. Canadian Task Force on Preventive Health Care. New grades for recommendations from the Canadian Task Force on Preventive Health Care. Can Med Assoc J 2003;169(3):207-8.

† Recommendations included in these guidelines have been adapted from the Classification of Recommendations criteria described in the Canadian Task Force on Preventive Health Care.

COST ANALYSIS

Overall, vaccination against high-risk human papillomavirus (HPV) types 16 and 18 and low-risk types 6 and 11 is cost-effective in a wide range of models with a wide range of assumptions. HPV vaccination can offer substantial health benefits, but at a cost—about US $24,000 per quality adjusted life year (QALY) gained, according to the US Markov model of vaccinating 12-year-old girls against HPV 16 and 18 with lifetime protection. However, the estimated cost per QALY gained with female-only vaccination is more favourable when the prevention of genital warts is included by vaccinating against HPV types 6 and 11 as well—about Can $15,000 according to the Canadian based model with vaccine efficacy of 100% and age 12 years for the start of vaccination. With the available published information, including that from the only government agency report published to date, the most significant avoided costs with HPV vaccination would be those of precancerous conditions of the cervix and nonmalignant disease. Cervical atypia and cancers would represent up to 55% of all costs avoided annually. Genital warts and RRP would make up another 36%.

METHOD OF GUIDELINE VALIDATION

Internal Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

These guidelines were prepared by the human papillomavirus (HPV) Consensus Guidelines Committee and approved by the Executive and Council of the Society of Obstetricians and Gynaecologists of Canada.

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

The grades of recommendations (A-E and L) and levels of evidence (I, II-1, II-2, II-3, and III) are defined at the end of the "Major Recommendations" field.

1. Government agencies should advocate for public funding to evaluate the cost-benefit analyses reported thus far for the human papillomavirus (HPV) vaccines. **IIIA**
2. Additional sensitivity analyses of HPV vaccines should be done urgently, along with examination of the cost-effectiveness of male vaccination in alternative strategies, such as with different ages at vaccination and with catch-up vaccination. **IIIA**
3. HPV vaccination is recommended for females aged 9 to 26 years against high-risk HPV types 16 and 18 for prevention of cervical cancer. **IA**
4. HPV vaccination is recommended for females aged 9 to 26 against low-risk HPV types 6 and 11 for prevention of external genital warts. **IA**

Definitions:

Levels of Evidence*

I: Evidence obtained from at least one properly designed randomized controlled trial.

II-1: Evidence obtained from well-designed controlled trials without randomization.

II-2: Evidence obtained from well-designed cohort or case–control analytic studies, preferably from more than one center or research group.

II-3: Evidence obtained from multiple time series with or without the intervention. Dramatic results in uncontrolled experiments also could be regarded as this type of evidence.

III: Opinions of respected authorities, based on clinical experience, descriptive studies, or reports of expert committees.

*The quality of evidence reported in these guidelines has been adapted from The Evaluation of Evidence criteria described in the Canadian Task Force on Preventive Health Care.

Grades of Recommendations* †

A. There is good evidence to recommend the clinical preventive action

B. There is fair evidence to recommend the clinical preventive action

C. The existing evidence is conflicting and does not allow to make a recommendation for or against use of the clinical preventive action; however, other factors may influence decision-making

D. There is fair evidence to recommend against the clinical preventive action

E. There is good evidence to recommend against the clinical preventive action

L. There is insufficient evidence (in quantity or quality) to make a recommendation; however, other factors may influence decision-making

* Woolf SH, Battista RN, Angerson GM, Logan AG, Eel W. Canadian Task Force on Preventive Health Care. New grades for recommendations from the Canadian Task Force on Preventive Health Care. Can Med Assoc J 2003;169(3):207-8.

† Recommendations included in these guidelines have been adapted from the Classification of Recommendations criteria described in the Canadian Task Force on Preventive Health Care.

CLINICAL ALGORITHM(S)

None provided

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The type of supporting evidence is identified and graded for each recommendation (see "Major Recommendations").

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

- Appropriate human papillomavirus (HPV) vaccination for prevention of HPV infection and HPV associated diseases
- Decreased clinical, psychological, and economic burden of HPV infection and HPV-related disease

POTENTIAL HARMS

Not stated

QUALIFYING STATEMENTS

QUALIFYING STATEMENTS

This document reflects emerging clinical and scientific advances on the date issued and is subject to change. The information should not be construed as

dictating an exclusive course of treatment or procedure to be followed. Local institutions can dictate amendments to these opinions. They should be well documented if modified at the local level. None of these contents may be reproduced in any form without prior written permission of the Society of Obstetricians and Gynaecologists of Canada (SOGC).

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

An implementation strategy was not provided.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Staying Healthy

IOM DOMAIN

Effectiveness

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

Lalonde A. Cost-benefit analysis of HPV vaccination. In: Canadian consensus guidelines on human papillomavirus. J Obstet Gynaecol Can 2007 Aug;29(8 Suppl 3):S43-54. [29 references]

ADAPTATION

Not applicable: The guideline was not adapted from another source.

DATE RELEASED

2007 Aug

GUIDELINE DEVELOPER(S)

Society of Obstetricians and Gynaecologists of Canada - Medical Specialty Society

SOURCE(S) OF FUNDING

The development of this consensus guideline was supported by unrestricted educational grants from Cytyc Canada, Digene Corporation, Graceway Canada, GlaxoSmithKline Inc., Merck Frosst Canada Ltd., and Roche Diagnostics Canada.

GUIDELINE COMMITTEE

HPV Consensus Guidelines Committee

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FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

Disclosure statements have been received from all members of the committees.

ENDORSER(S)

Canadian Association for Adolescent Health - Medical Specialty Society
Canadian Pediatric and Adolescent Gynaecology and Obstetrics Committee - Medical Specialty Society
Federation of Medical Women of Canada - Professional Association
Quebec Association of Pediatricians - State/Local Government Agency [Non-U.S.]
Society of Canadian Colposcopists - Professional Association
Society of Gynecologic Oncologists of Canada - Disease Specific Society

GUIDELINE STATUS

This is the current release of the guideline.

GUIDELINE AVAILABILITY

Electronic copies: Available in Portable Document Format (PDF) from the Society of Obstetricians and Gynaecologists of Canada Web site.

Print copies: Available from the Society of Obstetricians and Gynaecologists of Canada, La société des obstétriciens et gynécologues du Canada (SOGC) 780 promenade Echo Drive Ottawa, ON K1S 5R7 (Canada); Phone: 1-800-561-2416

AVAILABILITY OF COMPANION DOCUMENTS

None available

PATIENT RESOURCES

None available

NGC STATUS

This NGC summary was completed by ECRI Institute on July 7, 2009. The information was verified by the guideline developer on July 14, 2009.

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